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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,656	02/27/2006	Richard Joseph Fagan	C&R-109	2922

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EXAMINER	
KOSSON, ROSANNE	
ART UNIT	PAPER NUMBER
1652	

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10/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,656	FAGAN ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *47-67* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups 1-4, claim(s) 47(a), 47(i), 47(j), 66 and 67, drawn to a defensin polypeptide and a pharmaceutical composition comprising the polypeptide. Group 1 is SEQ ID NO:6; Group 2 is SEQ ID NO:8; Group 3 is SEQ ID NO:14; Group 4 is SEQ ID NO:16.

Groups 5-8, claim(s) 47(b) 47(c), 47(d), 47(i), 47(j), 47(k), 47(l) and 47(m), drawn to polynucleotide encoding a defensin protein, a pharmaceutical composition comprising the polynucleotide and a kit comprising a first container comprising a polynucleotide probe for a polynucleotide encoding the defensin polypeptide and a second container comprising primers for amplifying the polynucleotide encoding the defensin polypeptide. Group 5 is SEQ ID NO:5; Group 6 is SEQ ID NO:7; Group 3 is SEQ ID NO:13; Group 4 is SEQ ID NO:15.

Groups 9-12, claim(s) 47(e)(1) and 47(i), drawn to a ligand that is not an antibody and that specifically binds to a defensin polypeptide and a pharmaceutical composition comprising the ligand. Group 9 is a ligand that binds to SEQ ID NO:6; Group 10 is a ligand that binds to SEQ ID NO:8; Group 11 is a ligand that binds to SEQ ID NO:14; Group 12 is a ligand that binds to SEQ ID NO:16.

Groups 13-16, claim(s) 47(e)(2), 47(i) and 47(n), drawn to an antibody that specifically binds to a defensin polypeptide, a pharmaceutical composition comprising the antibody and a kit comprising the antibody. Group 13 is an antibody that binds to SEQ ID NO:6; Group 14 is an antibody that binds to SEQ ID NO:8; Group 15 is an antibody that binds to SEQ ID NO:14; Group 16 is an antibody that binds to SEQ ID NO:16.

Groups 17-20, claim(s) 47(f)(1) and 47(i), drawn to a compound that increases the level of expression or the activity of a defensin polypeptide and a pharmaceutical composition comprising the compound. Group 17 is a compound that increases the expression/activity of SEQ ID NO:6; Group 18 is a compound that increases the expression/activity of SEQ ID NO:8; Group 19 is a compound that increases the expression/activity of SEQ ID NO:14; Group 20 is a compound that increases the expression/activity of SEQ ID NO:16.

Groups 21-24, claim(s) 47(f)(2) and 47(i), drawn to a compound that decreases the level of expression or the activity of a defensin polypeptide and a pharmaceutical composition

comprising the compound. Group 21 is a compound that decreases the expression/activity of SEQ ID NO:6; Group 22 is a compound that decreases the expression/activity of SEQ ID NO:8; Group 23 is a compound that increases the expression/activity of SEQ ID NO:14; Group 24 is a compound that increases the expression/activity of SEQ ID NO:16.

Groups 25-28, claim(s) 47(g), 47(h) and 47(i), drawn to a compound that binds to a defensin polypeptide without having any biological effect on the polypeptide and a pharmaceutical comprising the compound (presumably the composition has other biological effects). Group 25 is a compound that binds to SEQ ID NO:6; Group 26 is a compound that binds to SEQ ID NO:8; Group 27 is a compound that binds to SEQ ID NO:14; Group 28 is a compound that binds to SEQ ID NO:16.

Groups 29-32, claim(s) 47(o), drawn to a transgenic non-human animal that expresses a higher level or a lower level of a human defensin polypeptide. Group 29 is a non-human animal that expresses SEQ ID NO:6; Group 30 is a non-human animal that expresses SEQ ID NO:8; Group 31 is a non-human animal that expresses SEQ ID NO:14; Group 32 is a non-human animal that expresses SEQ ID NO:16.

Groups 33-36, claim(s) 47(o), drawn to a knock-out non-human animal that does not express a human defensin polypeptide. Group 33 is a non-human animal that does not expresses SEQ ID NO:6; Group 34 is a non-human animal that does not express SEQ ID NO:8; Group 35 is a non-human animal that does not express SEQ ID NO:14; Group 36 is a non-human animal that does not expresses SEQ ID NO:16.

Groups 37-72, claim(s) 48(first recited use), 53, 54, 61 and 62, drawn to a method of diagnosing a disease in a patient. Group 37 is a method of using the composition of Group 1; Group 38 is a method of using the composition of Group 2; Group 72 is a method of using the composition of Group 36, etc.
Groups 45-52 also include claim 55. Groups 41-44 also include claims 56-60.

Groups 73-108, claim(s) 48(second and third recited uses), 49(i) and 50-52, drawn to a method of treating a disease in a patient or a method of monitoring that treatment. Group 73 is a method of using the composition of Group 1; Group 74 is a method of using the composition of Group 2; Group 108 is a method of using the composition of Group 36, etc.
Groups 73-76 also include claim 49(a). Groups 77-80 also include claims 49(b), 49(c) and 49(d). Groups 81-84 also include claim 49(e)(1). Groups 85-88 also include claim 49(e)(2). Groups 89-92 also include claim 49(f)(1). Groups 93-96 also include claim 49(f)(2). Groups 97-100 also include claims 49(g) and 49(h). Groups 73-110 also include claim 63.

Groups 109-144, claim(s) 48(fourth and fifth recited uses), drawn to a method of screening for a compound that is effective in treating or diagnosing a disease and a method of identifying that compound. Group 109 is a method of using the composition of Group 1; Group 110 is a method of using the composition of Group 2; Group 144 is a method of using the composition of Group 36, etc. Groups 109-116 also include claim 64. Groups 137-140 also include claim 65.

The inventions listed as Groups 1-144 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The requirement of unity of invention is not fulfilled because there is no technical relationship among these inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant claims, there is no technical feature that is shared among all of the Groups, because the polypeptide claims encompass fragments, which read on individual amino acids, and "functional equivalents" of these individual amino acids, the meaning of which cannot be determined. Because no technical feature links all the groups, there is no common technical feature that can be special, i.e., novel and not obvious. Moreover, single amino acids are known in the art. Thus, they are not novel and are obvious. Therefore, a technical relationship is lacking among the claimed inventions involving one or more special technical features.

Further, an international application containing claims to different categories of inventions will be considered to have unity of invention if the claims are drawn only to one of certain combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
(4) A process and an apparatus or means specifically designed for carrying out the said process; or
(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process (see 37 CFR 1.475(b)-(d)). In the instant case, the claims are drawn to an extremely large number of products and processes, only a particular combination of which including Group 1 may be considered for unity of invention, i.e., Group 1 and Group 37, (the first named product and the first named process of using the product). Other groups are drawn to additional products and processes, and other combinations do not comply with the aforementioned Rules. But, because a corresponding special technical feature is not present, Groups 1 and 37 cannot be considered to have unity of invention.

Regarding the different claimed sequences, Applicants must choose **ONE** polypeptide or one polynucleotide from among those claimed as indicated in the different groups above. Each sequence is a distinct invention requiring separate searches. THESE ARE NOT SPECIES. Each sequence is a chemically, structurally and functionally distinct molecule. Therefore, the each of the polynucleotides is patentably distinct.

Moreover, each sequence requires a separate set of searches. Applicants should note that searching each sequence imposes a serious search burden. Currently, there are approximately eight different databases that accompany the results of a search for <u>one</u> discrete

amino acid or nucleic acid sequence, and each result set from a particular database must be carefully considered. Each set of prior art has its own considerations with respect to anticipation and obviousness. Hence, the search for even two different polypeptides or polynucleotides in the databases, in addition to searching the organic molecule databases, would require extensive searching and review. Therefore, these inventions are patentably distinct.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows.

a) If Applicant elects one of Groups 21-24, Applicant must elect one of the compounds listed in claim 47(h) (e.g., a natural substrate).

b) If Applicant elects one of Groups 97-100, Applicant must elect one of the compounds listed in claim 49(h) (e.g., a natural substrate).

c) If Applicant elects one of Groups 73-108, Applicant must elect one of the diseases listed in claim 50.

d) If Applicant elects one of Groups 73-108, Applicant must elect either the symptom of under-expression in the disease state, claim 51, or over-expression in the diseased state, claim 52. one of the diseases listed in claim 50.

e) If Applicant elects one of Groups 37-72, Applicant must elect one of the diseases listed in claim 61.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted in each of parts (a) – (e) above if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including

any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 47, 48, 49 and 53.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons. Each compound has a different structure, different biological properties, a different function and a different effect. Each disease has a different pathology, requires different diagnostic techniques and different treatments and affects a different patient population. Each species requires a different search and has different considerations with respect to patentability.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The

examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached at 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652
rk/2008-10-17

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657